



PRESCRIBING INFORMATION

TERSA-TAR[®] coal tar (tar distillate 3%) Shampoo

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TERSA-TAR®

coal tar (tar distillate 3%)

INDICATIONS AND CLINICAL USE

TERSA-TAR® is an antipruritic and keratoplastic (removes scaling) used in the treatment of dandruff, eczema, cradle cap, itching scalp, psoriasis, and seborrheic dermatitis.

CONTRAINDICATIONS

TERSA-TAR® is contraindicated in individuals with known hypersensitivity to coal tar or to any of the excipients in the preparation.

TERSA-TAR® should not be used to treat infected open skin lesions or sore or acute pustular psoriasis.

WARNINGS AND PRECAUTIONS

TERSA-TAR® is for external use only. TERSA-TAR® is for cutaneous use only. Avoid contact with the eyes. If contact occurs rinse eyes thoroughly with water. Coal tar preparations, such as TERSA-TAR® may cause irritancy; therefore contact with sensitive areas, such as broken or very inflamed skin, should be avoided. If irritation develops, treatment should be discontinued.

TERSA-TAR® can stain skin and clothes. Contact with clothes should be avoided. Skin stains will wear off after treatment is stopped.

In rare instances, temporary hair colour changes may occur.

As TERSA-TAR[®] may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure of the scalp to sunlight should be avoided or minimized.

TERSA-TAR[®] should be used with caution if the patient is also taking drugs known to be photosensitizers (e.g. thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulphonamides) because of the increased possibility of augmented photosensitivity.

Consult a health care practitioner if condition worsens or does not improve after regular use of this product.

Consult a health care practitioner prior to use in children under 2 years of age.

Pregnancy and Lactation

Fertility

There are no data on the effects of topical coal tar preparations on human fertility.

Pregnancy

There are limited data from the use of coal tar preparations in pregnant women.

Coal tar has been shown to be fetotoxic and teratogenic to the offspring of laboratory animals when administered topically, orally or by inhalation at high and maternally toxic doses.

Use of coal tar preparations during pregnancy should only be considered if the expected benefit to the mother outweighs the potential risk to the fetus.

The use of coal tar products should be avoided in the first trimester of pregnancy.

Lactation

The safe use of topical coal tar preparations during lactation has not been established.

It is not known whether the topical application of coal tar preparations could result in sufficient systemic absorption to produce detectable amounts in breast milk.

Use of coal tar preparations during lactation should only be considered if the expected benefit to the mother outweighs the potential risk to the infant.

If used during lactation, patients should be advised to ensure that any residual product is fully washed off the breast prior to breast-feeding in order to avoid accidental ingestion by the infant.

ADVERSE REACTIONS

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: rare ($\geq 1/10,000$ and $< 1/1,000$).

Post-marketing data

Immune system disorders

Rare: Hypersensitivity (including pruritus, angioedema, dyspnea)

Eye disorders

Rare: Eye irritation

Skin and subcutaneous tissue disorders

Rare: Alopecia, dermatitis, hair colour changes, abnormal hair texture, photosensitivity reaction, skin irritation (including dry skin, erythema, and skin burning sensation).

General disorders and administration site conditions

Rare: Application site hypersensitivity, application site pain, application site rash, localised edema.

DOSAGE AND ADMINISTRATION

Adults and Children aged 12 years and older

TERSA-TAR[®] is for topical application to the scalp.

Apply evenly to wet hair and massage for several minutes for rich lather. Rinse. Repeat and massage for 3 to 5 minutes. Rinse well. Shampoo 2 to 3 times per week or as directed by your physician.

Children

The safety and efficacy of TERSA-TAR[®] in children under 12 years of age have not been established. TERSA-TAR[®] should be used with caution in children and only on the recommendation of a doctor or pharmacist.

SYMPTOMS AND TREATMENT OF OVERDOSE

Symptoms

Topical coal tar overdose may increase the rate of skin irritation and photosensitivity. (see Adverse Reactions).

Treatment

Management should be as clinically indicated or as recommended by the national poisons centre, where available.

For management of a suspected overdose, contact your regional Poison Control Centre.
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DESCRIPTION AND COMPOSITION

Description:

TERSA-TAR[®] is an amber transparent liquid.

Composition:

Each gram of TERSA-TAR[®] (coal tar as tar distillate 3%) contains 30.0 mg of tar distillate. TERSA-TAR[®] also contains D&C yellow #8, edetate disodium, fragrance #6218-1, glycol ether DE, isopropyl alcohol, lauramide DEA, methyl paraben, PEG 600

distearate, phosphoric acid (85%), propyl paraben, purified water and triethanolamine lauryl sulphate.

AVAILABILITY

TERSA-TAR[®] (coal tar as tar distillate 3%) is available in 150 mL and 450 mL bottles.

STORAGE

Store at a controlled room temperature 15 - 30°C.